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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/820,221

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Donald L. Bockelman

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/820,221

Applicant(s)

BOCKELMAN, DONALD L.

Examiner

Medina A. Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24 are pending and are examined.

Claim Objections

Claims 1, 2, 9, 11-13, 17, 19, and 23 are objected to for reciting incomplete accession information.

Claim 6 is objected to for failing to further limit parent claim 2 because the corn plant of claim 2 does not contain nuclear or cytoplasmic gene conferring male sterility.

The specification is objected to for including blank spaces on page 22, lines 7-8.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-11, 18-19 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 18 are indefinite in the recitation of "derived" because what is encompassed by the derivative is unknown. Clarification is required to more clearly define the metes and bounds of the claims.

Claim 11 is indefinite in the recitation of "capable" which implies the plant may or may not express all the characteristics of the corn variety 1029010. The specification does not describe the conditions under which the plant may or may not express the characteristics. Therefore, the metes and bound of the claim is unclear.

Claims 19 and 23 are indefinite in the recitation of "mappable genetic loci" which

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is not defined in the specification. Since the phrase is not art-recognized, it is open to individual interpretations, thus one would not know what is encompassed by the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the seed claimed is essential to the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be readily available to the public. The specification does not disclose a reproducible method to obtain the exact same seed and it is unclear if the seed is readily available to the public.

The deposit statement on page 22 of the specification for the claimed variety soybean variety 1029010 is noted. However, there is no indication that the seed has been deposited and no indication that the seed is available to the public. A deposit of at least 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit has been made under the terms of the Budapest Treaty, then an

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affidavit or declaration by Applicants, or statement by an attorney of record over his or her signature and registration number, stating that the seed has been deposited under the Budapest Treaty and the seed will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. See 37 C.F.R. 1.808-1.809 for additional explanation of these requirements.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 days or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see C.F.R. 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method of producing a conversion of the corn variety 1029010 to express at least one new trait, the method comprising crossing a first corn plant comprising a genetic locus that confers at least one trait with the corn variety 1029010 to produce seed comprising alleles from both parents and further comprising the genetic locus that confers the new trait; backcrossing F1 plants produced from said seed with a plant of the corn variety 1029010 and repeating said backcrossing step for at least one additional generation to produce a converted plant of the corn variety 1029010 comprising the genetic locus that confers the new trait, and harvesting the seed of the converted plant. The claims also encompass specific new traits and plants produced by said method.

The specification defines "converted plants" as those corn plants which are developed by backcrossing technique, wherein essentially all of the desired morphological and physiological characteristics of a variety are recovered in addition to a genetic locus transferred into the variety via the backcrossing technique. However, the specification does not teach any 1029010 plant comprising single locus conversions produced by crossing.

The practice of crossing two plant varieties, each expressing two different

desired traits, for example, to obtain a single variety that expresses both desired traits is well established. It involves crossing of two parents which contribute half of their entire genetic composition in an uncontrolled, random manner. However, the practice of conversion produced by backcrossing, wherein the resultant plant retains all of its morphological and physiological traits in addition to exhibiting the single trait conferred by the introduced single locus is unpredictable.

Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single locus conversion plant with a desired trait (column 3, lines 26-46). The gene conferring the desired trait may be properly expressed in some genetic backgrounds, but not expressed in other backgrounds, so that the trait would not be predictably conferred. Thus, a gene conferring disease resistance in one donor variety of corn may not function properly when transferred into 1029010, due to the interactions with all of the other 1029010 genes that were not present in the original donor variety.

Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single locus conversion but otherwise maintaining all of

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the desired genes and traits of the recipient parent, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several varieties become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Linkage drag refers to the close proximity on the chromosome of genes conferring undesirable traits to a gene conferring a desirable trait. Due to such close proximity, it is virtually impossible to remove the genes conferring the undesirable trait from progeny which were selected for the desirable trait. The situation becomes even more complex when it involves traits such as seed yield which are affected by multiple genes on multiple chromosomes, i.e. "quantitatively inherited" traits.

Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, variety 1 to page 1816, column 1, variety 1). Epistasis refers to the unpredictable interaction of various genes with each other. Such epistasis may result in the inhibition of one gene by another, so that a gene conferring insect resistance, which functions in a particular donor plant, would not function in 1029010 or a progeny thereof, due to the presence of other genes in 1029010 or the progeny which inhibit the function of the insect resistance gene. In quantitative traits, which are governed by the combined action of many genes, each conferring a small effect on the trait, the situation

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is even more pronounced. In quantitative traits such as yield, high yield of 200 bushels per acre may be the result of the contribution of 20 genes on different chromosomes, each conferring an incremental yield increase of 10 bushels per acre, when acting in an additive fashion. Due to epistatic interactions with other genes in other genetic backgrounds, even if all 20 genes were present, they would not act additively to cause a yield of 200 bushels per acre. Perhaps half of the genes would be inhibited, giving a low yield of only 100 bushels per acre. Furthermore, some of the 20 genes might not even be transmitted to the progeny, due to random gene segregation as well as the selection against undesirable traits conferred by genes linked to some of the 20 high yield genes.

Applicant has not provided guidance for the introduction of at least one new trait from a multitude of non-disclosed and uncharacterized donor breeding partners into 1029010, by backcrossing or by any other means, wherein the introduction of the desired trait should result in successful expression of the desired trait but should not interfere with the expression of the remaining 1029010 traits. Furthermore, no guidance has been provided for preventing the introduction of unwanted genetic material conferring undesirable agronomic traits from the donor breeding partner into 1029010.

Applicant has not provided guidance regarding the morphological or genetic composition of a multitude of non-exemplified breeding partners in multiple crosses with 1029010 parents over multiple generations as claimed in claim 18. Given the lack of guidance regarding the genetic composition or morphological traits of the non-disclosed breeding partners, no guidance has been provided for methods of using the resultant

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progeny plants with unknowable morphological and genetic characteristics.

Furthermore, no guidance has been provided for methods of using hybrids produced by crossing 1029010 with a multitude of non-disclosed parents, since the hybrids themselves have not been reduced to practice or characterized morphologically or genetically, throughout the broad scope of the claims.

In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of backcross conversions taught in the prior art, in order to yield the claimed plants which differ from 1029010 only in comprising a single locus conversion and by the expression of a single trait.

In addition, no guidance has been provided for the isolation or characterization of a multitude of "transgenes" conferring a multitude of traits, or corn plants containing a multitude of unspecified transgenes conferring unspecified, if any, traits, as claimed in claims 15 and 17. Claims 15-17 are further rejected because "a transgene" introduced into the plant by genetic transformation includes those introduced by backcrossing as rejected above. Further, the transgene may encode any product having any function, and can therefore affect the other traits expressed by 1029010. For example, if the single locus encodes a transcription factor, the expression of numerous genes may be affected, which in turn would affect numerous traits expressed by 1029010, including yield, flowering date, maturity date, etc.

Therefore, given the lack of guidance in Applicants' specification regarding transfer of traits by backcrossing in Applicant's corn variety, the lack of guidance

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regarding the isolation of any and all transgenes that confer variety traits or their evaluation in particular corn genetic background, the state of the art and the unpredictability inherent in transferring by backcrossing, and lack of working examples, one skilled in the art would not be able to make and/or use the invention, without undue experimentations.

Written Description

Claims 15-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to corn plants of variety 1029010 further comprising a multitude of undescribed transgenes and a method of producing transgenic plants with said undescribed transgenes. The claims are also drawn to a method of producing inbred corn plant derived from the exemplified variety, said method employs hybrid seed and plants and subsequent generation plants thereof which are not described in the specification. The claims are further drawn to hybrid seed and plants produced by crossing corn plants of variety 1029010 with unidentified corn plants. Applicant, however, only describes variety corn variety 1029010 having specific genotypic and phenotypic characteristics that distinguish the variety from other corn plants and a single F1 hybrid, NA6107RR, produced by crossing 1029010 plant with known inbred corn plant 1294213.

The Federal Circuit court stated that a written description of an invention

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"requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other material". *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). The court also stated "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of is not a description of that material". *Id.* Further, the court stated that to adequately describe a claimed genus, Applicant must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of members of the genus".

Applicant has not described the morphological and/or genotypic characteristics for all hybrid corn plants and seeds produced by crossing corn variety 1029010 with another unidentified corn plant. Applicant only describes corn variety 1029010 having specific genotypic and phenotypic characteristics that distinguish variety 1029010 from other corn variety. Because a number of uncharacterized breeding partners have been employed, substantial variation in structure and phenotypes are expected among F1 plants/seed. Therefore, the disclosure of a single corn variety, namely, 1029010 and a single hybrid produced thereof would not provide adequate written description for all F1 hybrid or method for using F1 plants to produce subsequent generation plants, absent further description. Accordingly, written description requirement is not satisfied.

Regarding the transgenes, claims 15 and 17 do not specify the sequence of the transgene; the source of the transgene which may be from bacteria, fungi, animals or plants; or the encoded product, such as a multitude of proteins or enzymes, or reverse-orientation RNA molecules which inhibit the expression of other genes, etc. These

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claims do not even specify the traits which result from the introduction and successful expression, if any, of the transgene. The specification does not describe transforming 1029010 cells with all transgenes. As broadly interpreted, the claimed plants and method encompass introducing any type of transgene into 1029010, including those that have not been isolated at the time the application was filed. The prior art shows that hundreds of nucleotide sequences encoding products that confer various types of plant traits have been isolated at the time the instant invention was filed. The claims do not place any limit on the transgenes to be introduced, and encompass transgenes for plant traits that have yet to be isolated. For example, isolated genes whose products confer yield enhancement and enhanced nutritional quality are not known in the prior art. One skilled in the art would not know Applicant was in possession of the claimed method and claimed plants if the transgene whose product confer a desired trait has not been isolated at the time the instant invention was made.

Remarks

The claims are free of the prior art of record, given that the prior art does not teach or fairly suggest corn variety having all the morphological and physiological characteristics of variety 1029010 as listed in Table 1.

No claim is allowed.

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307,

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respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

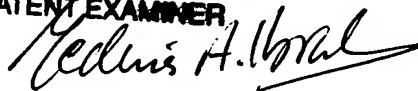
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9/30/05

Mai

MEDINA A. IBRAHIM
PATENT EXAMINER

A handwritten signature in black ink, appearing to read 'Medina A. Ibrahim', written over the printed name and title.